STATE OF VERMONT

HUMAN SERVICES BOARD

In re) Fair Hearing No. 13,752 &) 13,753

Appeal of)

)

INTRODUCTION

The petitioners (whose appeals were consolidated by stipulation of the parties) appeal the decision by the Department of Social Welfare denying them medicaid coverage for pedicle screw spinal implant surgery. The issue is whether this is a covered service within the meaning of the pertinent regulations.

FINDINGS OF FACT

In lieu of an oral hearing the parties have submitted written arguments. The petitioners suffer from chronic severe lower back pain. Their physicians (both petitioners are patients of the same group of surgical associates) have recommended that they undergo surgery to insert an internal spinal fixation device known as a pedicle screw. The petitioners concede that pedicle screws have not been approved by the federal Food and Drug Administration (FDA) for use in the spinal area where their doctors have recommended they be inserted. Although there appears to be considerable controversy in the national medical community about this procedure, the Department does not appear to dispute that despite the lack of FDA approval pedicle screw surgery is performed on tens of thousands of patients annually in the United States. It also appears that the petitioner's physicians are experienced and have a successful track record in performing this surgery. There is no question that they do not consider the surgery to be "experimental", and that the petitioners' physicians strenuously disagree with the Department's decision of non-coverage. The Department does not appear to dispute that spinal fusion surgery (although not utilizing pedicle screws) is "medically necessary" for the petitioners. The basis of the Department's decision appears to be that any procedure not approved by the FDA cannot be covered under medicaid.

ORDER

The Department's decision is reversed and the matter remanded to the Department to make a determination specific to the petitioners whether the surgery in question is "justified".

REASONS

The petitioners first argue that pedicle screw surgery is covered under the medicaid regulations as a "prosthetic device" under Medicaid Manual (M.M.) § M844. This can be rejected at the outset. A prosthesis is a "replacement, corrective, or supportive" device for a missing, deformed, or

malfunctioning body part. See 45 C.F.R. § 440.120(c). A pedicle screw, as defined by the petitioners' doctors and by the medical literature, is a surgically implanted device used to facilitate surgical spinal fusion. There is no basis in either the medical terminology or the plain meaning of the regulations to conclude that such devices fall under the medicaid definition of a "prosthesis".

Under the medicaid regulations all surgical procedures fall under the category of "Physician Services". M.M. §§ M610 et seq. Contrary to the Department's assertion, however, these regulations require medicaid coverage for all physician services that are "medically necessary". § M610. The preliminary issue in these cases is whether the service in question falls under § M618, "Procedures Requiring Prior Authorization", which provides as follows:

Routine payment will not be made for procedures falling into one or more of the following four categories. Written justification will have to be made by the physician and approved by the Medicaid Division before service is rendered.

1. New procedures of unproven value; or

2. Established procedures of questionable current usefulness; or

3. Procedures which tend to be redundant when performed in combination with other procedures; or

4. Diagnostic procedures which are unlikely to provide a physician with additional information when they are repeated.

Identification of such procedures is made through the Medical Necessity Program begun by Blue Shield with the assistance of the American College of Physicians, American College of Radiology and American College of Surgeons. Also participating, is the American Academy of Family Practice, Council of Medical Specialties, American Hospital Association and American Associations of Medical Colleges.

The Board concludes that any procedure not approved by the FDA is sufficient under the above regulation to at least establish that it is a "new procedure of unproven value" that requires prior authorization. Thus, the Board need not reach the issue of whether pedicle screw surgery should still be considered "experimental".

The fact that prior authorization is required, however, does not mean that such a procedure is automatically excluded from coverage under the regulations. Under § M618, the Department is required to make a determination whether there is "written justification" for that procedure--despite the fact that the procedure is "unproven". Moreover, as noted above, the regulations require that such a determination be based on "medical necessity". This entails a detailed risk/benefit analysis of the procedure specific to the individual recipient who requests it.

The petitioners have presented what-appears-to-be-compelling medical documentation that the procedure is necessary, cost effective, and safe. Unless and until the Department can specifically counter that evidence, it must be concluded that it is abusing its discretion under the regulations by denying medicaid coverage solely on the basis of the lack of FDA approval.

At this point--i.e., before the Department has had the opportunity, in light of this opinion, to meet its obligation under the regulations--it is arguably premature and potentially dangerous for the Board to conclude that the petitioners have met the requirements of "written justification" under § M618, supra. However, inasmuch as the Department has not met its burden under the regulations to establish that the procedure in question is not "justified", the cases must at least be remanded to the Department to make that determination in accordance with this opinion and § M618.

On remand, the Department must specifically consider and respond to the opinions of the petitioners' physicians; and, if coverage is denied, the Department must provide the petitioners with a rationale that explains, inter alia, why the Department concludes that the risks of pedicle screw surgery outweigh the benefits outlined by the petitioners' doctors. If the Department cannot provide such a rationale, it must, under §§ 610 and 618, approve coverage for the surgery.(1)

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1. The fact that the Department may have delegated prior authorization determinations to a private contractor does not relieve it of its responsibility under the regulations to consider whether the procedure is "justified" and to provide a detailed rationale for any decision denying coverage.